

REMARKS/ARGUMENTS

Claims 1, 3-10, 18, 19, 29, and 31-33 are now pending in this application.

Claims 2, 11-17, 20-28, 30 and 34 have been canceled.

Claims 1, 9, 10, and 32 have been amended to more particularly point and distinctly claim the invention.

The amendments to claim 1 delete the transgenic limitations and incorporate a limitation contained within previously pending now canceled claim 2.

The amendments to claim 9 incorporate the language of claim 1 prior to the amendment thereby making claim 9 independent. The claim is further amended by deleting mouse descriptions. In the same manner claim 10 has been amended to delete certain mouse descriptions.

Claim 32 is amended in a manner similar to that of claim 9. Claim 32 has been made independent by incorporating the language contained within claim 1 prior to the amendment.

In that the claim amendments incorporate limitations contained within previously pending claims they do not raise new issues and these amendments are believed to be proper under 37 C.F.R. §1.116. Accordingly, entry of the amendments is respectfully requested. No new matter is believed to be added.

**Double Patenting Rejection**

The claims were rejected under the judicially created doctrine of obviousness-type double patenting. Applicant does not acquiesce to the rejection. However, applicant wishes to expedite prosecution of this application. Accordingly, applicant has attached a Terminal Disclaimer with respect to co-owned U.S. Patent 6,020,537. Accordingly, the double patenting rejection is believed to have been rendered moot.

**35 U.S.C. §112 Rejection**

All of the previously pending claims except for claims 32 and 33 were rejected under 35 U.S.C. §112, first paragraph. The rejection is traversed as applied and as it might be applied to the presently pending claims. In essence, the rejection argues that the invention is not enabled except for situations when the transgenic mouse has both alleles of the PrP gene ablated and the inserted PrP gene is either

human, bovine or sheep. Although applicant does not acquiesce to this rejection amended claim 9 is limited to the embodiment the Examiner indicated as allowable. Accordingly, under the language provided within the rejection amended claim 9 is allowable.

Further, amended claim 32 was previously rejected only under the double patenting rejection which has been rendered moot by the attached Terminal Disclaimer – and the same was true with respect to claim 33. Now that claim 32 has been placed in independent form and the Terminal Disclaimer has been filed claims 32 and 33 are allowable in accordance with the language contained within the rejection.

In view of the above the only remaining issues are with respect to the enablement of independent claim 1 as well as its dependent claims.

Applicant understands how the rejection could be argued with respect to claims which are directed to a transgenic mouse *per se*. Applicant understands that the Patent Office has taken a relatively strict policy with respect to claims directed to transgenic animals *per se* in view of the unpredictability of such. However, the present claims are not directed to a transgenic mouse and are further not directed to a process for producing a transgenic mouse and still further are not directed to a process of producing any organism or genetic material. In view of such it is applicant's position that the 35 U.S.C. §112 arguments are not applicable to the presently claimed invention which is directed to a standardized prion preparation.

Applicant was the first to disclose and describe a standardized prion preparation of the type encompassed by claim 1. Applicant recognizes that the present disclosure only includes representative examples of how such a prion preparation might be produced. However, those skilled in the art could readily devise other processes for the production of such a standardized prion preparation. For example, one skilled in the art could isolate prions from a diseased brain of a human, cow or sheep, mix those isolated prions into a carrier, test the resulting preparation to determine that it does cause infection, determine its strain and determine the number of infectious units as well as the concentration of prions in the preparation. All of this could be done without the need for the preparation of a transgenic mouse. Accordingly, the amended claim 1 is believed to be fully enabled within the meaning of 35 U.S.C. §112. An indication of such is respectfully requested along with an indication that the application is in condition for allowance.

In the event that the Examiner finds that minor issues remain unresolved the Examiner is respectfully requested to contact the undersigned attorney at the indicated telephone number to arrange for an interview to expedite the disposition of this application.

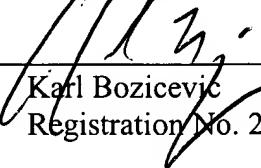
The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number UCAL-056CIP4.

Date:

13/July/04

Respectfully submitted,  
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